K071226
p 1 of 3

510(k) SUMMARY

JUN 29 2007

SUBMITTER INFORMATION

A. Company Name: Spectranetics Corporation, Inc.

B. Company Address: 96 Talamine Court
Colorado Springs, Colorado 80907

C. Company Phone: 719-633-8333 / 1-800-633-0960

D. Company Facsimile: 719 447 2040

E. Contact Person: Kelly Elliott
Vice President
Clinical Affairs and Regulatory Submissions

DEVICE IDENTIFICATION

A. Device Trade Name: TURBO-Booster™ Guiding Catheter

B. Device Common Name: Guiding Catheter or Guide Catheter

C. Classification Name: Percutaneous Catheter

D. Device Class: Class II (per 21 CFR 870.1250)

E. Device Code: DQY

IDENTIFICATION OF PREDICATE DEVICES

Spectranetics TURBO-Booster™ guiding catheters are substantially equivalent to many similar devices currently on the market. Spectranetics deems the Cordis Vista Brite Tip® Guiding Catheter (K971572) to be the primary predicate for the TURBO-Booster™. Additional predicates are the Scheidner Guider Softip® Guide Catheter (K980453) and the Boston Scientific Mach 1 Guiding Catheter (K020028).

DEVICE DESCRIPTION

The TURBO-Booster™ is comprised of a luer hub, strain relief, shaft, hydrophilic coating, and a tip. The strain relief acts as a transition point between the stiff luer hub and flexible shaft.

The shaft is comprised of three different components: an FEP inner liner, a stainless steel braid and a Pebax outer jacket. The stainless steep braid improves the torque response of the device and overall strength of the shaft.

The tip is constructed of Pebax with varying stiffness (durometer). The proximal portion of the tip includes the biasing ramp that offsets the laser catheter to create the bias. The distal portion provides an atraumatic tip for the device.

A hydrophilic coating is applied to the outer surface of the device to reduce friction between the device and the crossover sheath. It also provides lubrication during use through the body's vasculature.

The TURBO-Booster™ is used to bias (offset) a Spectranetics laser catheter from the central axis (guiding wire axis) during ablation. This allows for a larger lumen to be created than can be created with a laser catheter alone.

INTENDED USE

The Spectranetics TURBO-Booster™ guiding catheter is designed for directing and supporting Spectranetics laser catheters for use in the treatment of infrainguinal stenoses and occlusions.

COMPARISON TO PREDICATE DEVICES

Spectranetics brand TURBO-Booster™ guiding catheters are equivalent in form, fit, and function to the previously marketed Cordis Vista Brite Tip, Schneider Guider Softip, and Boston Scientific Mach 1 guiding catheters, the cited predicates. All of these guide catheters help to guide and position other interventional devices within a patients' vasculature, and in particular the peripheral vascular.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

TURBO-Booster™ guiding catheters are built from the same components and materials of construction as other, already-marketed, Spectranetics products. Therefore, biocompatibility of both component materials and the finished TURBO-Booster™ guiding catheters have been previously confirmed in accord with the ISO 10993 series of standards, Biological Evaluation of Medical Devices. Spectranetics conducts and maintains valid ethylene oxide sterilization processes in accord with ISO 11135, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. Package integrity is initially validated in conjunction with sterilization studies.

Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. All TURBO-Booster™ guiding catheter models meet or exceed both Spectranetics in-house requirements, and requirements listed in ISO 10555-1, Sterile, Single-use Intravascular Catheters – Part 1: General Requirements.

CLINICAL DATA

Clinical data were collected in support of safety and efficacy for Spectranetics brand TURBO-Booster™ guiding catheters. Approximately sixty (60) patients enrolled in the CELLO Study (CLiRpath Excimer Laser System to Enlarge Lumen Openings) approved as IDE #G060015. No major adverse events were recorded, and the TURBO-Booster™ successfully facilitated placement of laser catheters in 96.8% of the trial cases.

CONCLUSION

The above statements establish substantial equivalence between the TURBO-Booster™ and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Spectranetics Corp., Inc.
c/o Ms. Kelly W. Elliot, RN, MS
Vice President Clinical Affairs and Regulatory Submissions
96 Talamine Court
Colorado Springs, CO 80907-5186

SEP 18 2013

Re: K071226
Trade/Device Name: 8Fr and 7Fr Turbo Booster Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: May 1, 2007
Received: May 3, 2007

Dear Ms. Elliot:

This letter corrects our substantially equivalent letter of June 29, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7. Statement of Indication for Use

Device Name: TURBO-Booster™ Guiding Catheter

Indications for Use

The Spectranetics TURBO-Booster™ guiding catheter is designed for directing and supporting Spectranetics laser catheters for use in the treatment of infrainguinal stenoses and occlusions.

Not for use in the carotid and coronary vasculature.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071226